

## **POLICY CLARIFICATION**

### **Re: Tamper-resistant Prescription Pads**

The April 1, 2008 implementation of the tamper-resistant prescription pad requirements for written prescriptions billed to Medicaid has been successful thus far.

However, there are policy clarifications that seem appropriate based on the questions received thus far:

1. If a vendor has provided “tamper-resistant prescription pads” to you that do not meet all of the requirements of 902 KAR 55:105 for controlled substance prescription blanks, then you are not in compliance with Kentucky’s guidelines. The use of a non-compliant prescription blank will most likely be rejected at the pharmacy and/or it may generate a phone call to your office.
2. The requirements for the controlled substance prescription blanks used in Kentucky for nearly ten years, include a requirement that only one prescription can be written per prescription blank, and a requirement for a quantity check-off box that corresponds to the quantity prescribed to be marked as well. A prescription blank that attempts to include more than one prescription is non-compliant.

When Kentucky Medicaid issued our compliance requirements last fall, we communicated our policy decision to require the use of our current controlled substance prescription blanks. This decision was made to eliminate the need for three prescription blanks to be stocked – regular, controlled substance, and “Medicaid only” pads.

Please click on this link to review all of the requirements related to the controlled substance prescription blanks, which are now also required for all written Medicaid prescriptions. <http://www.lrc.ky.gov/kar/902/055/105.htm>

We will continue to issue and post policy clarifications, if necessary, to facilitate a smooth implementation of these new requirements. Thank you for your commitment to compliance with these new requirements.



**CABINET FOR HEALTH AND FAMILY SERVICES  
DEPARTMENT FOR MEDICAID SERVICES**

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**Mark D. Birdwhistell**  
Secretary

**Shawn M. Crouch**  
Commissioner

September 14, 2007

**TO: All KyHealth Choices Providers:  
General Provider Letter: A-77**

**RE: New Tamper-resistant Prescription Pad Requirements Effective 10/1/07**

Dear **KyHealth Choices** Provider:

The U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007, was signed into law on May 25, 2007. One of the provisions of the legislation mandates the use of tamper-resistant prescription pads for written prescriptions for all outpatient medications, including over-the-counter medications, reimbursed by state Medicaid programs. This provision is effective October 1, 2007.

On August 17, 2007, the Centers for Medicare & Medicaid Services (CMS), issued a letter to State Medicaid Directors (<http://www.cms.hhs.gov/SMDL/downloads/SMD081707.pdf>) with guidance on implementing the new requirements. As part of that guidance, CMS has deemed that the current tamper-resistant pads mandated for controlled substance prescriptions in Kentucky will meet the requirement of the federal mandate at least until October 1, 2008 when further requirements will go into effect.

Thus, effective October 1, 2007, Medicaid outpatient medications will be reimbursable only if written outpatient and over-the-counter prescriptions are executed on a tamper-resistant pad that meets or exceeds the requirements of 902 KAR 55:105.  
(<http://www.lrc.ky.gov/kar/902/055/105.htm>)

Enforcement of the tamper-resistant prescription pads for Medicaid members begins on October 1, 2007. If a prescription isn't on the correct paper, pharmacies may refuse to fill the prescription, call the physician's office to obtain an oral prescription or opt to fill the prescription as an "emergency" situation, then follow-up with the physician's office to get the prescription information in an acceptable format. **To avoid delays in patient care, prescribers should make sure that they have an adequate supply of tamper-resistant prescription pads to meet the October 1 effective date.**



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For out-of-state prescriptions, pharmacies may accept the current required pads for controlled substances in Kentucky or the tamper-resistant pads that are approved by those states. Each state is working to issue instructions regarding their requirements for compliance with this new legislation.

There is a requirement for all states to be in compliance with all three requirements for tamper-resistant prescription pads by October 1, 2008. We will issue further guidance once we have determined what changes may be necessary, if any, for Kentucky to be in compliance at that time.

If you have any questions, please call 1-800-432-7005 for assistance.

Sincerely,

Shawn M. Crouch  
Commissioner

SMC/CB/CM/jlc00328

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## Questions & Answers

(Taken from Conference Call with CMS representatives on 8/29/07)

### **Re: Tamper-resistant Prescription Pads Effective 10/1/07 for Medicaid**

- ✓ Will facility-based prescriptions, which stay in the facility, have exceptions to the tamper-resistant (T-R) requirements?  
No, there will not be an exception for written prescriptions staying in a facility. If the prescription is reimbursable by Medicaid, then a T-R pad is needed.
- ✓ Many facilities use computer printer paper for their prescriptions – will they be exempt?  
No, there are many vendors selling computer printer paper that is compliant with the T-R law.
- ✓ If a patient in a long-term care facility has a telephone order transcribed by the nurse and it is given directly to the pharmacy (for example, given to a driver to give back to the pharmacy), does it need to be on a T-R pad?  
Yes. If the nurse called it in or faxed it to the pharmacy, then no. Yes, only if it's written and then taken to the pharmacy.
  - Will there be any further guidance on the definition of “industry recognized standards?”  
No, however, you can look at the eleven states that already have T-R requirements in place, since those states have defined industry recognized standards. The 11 states are California, Florida, Georgia, Idaho, Indiana, Kentucky, Maine, New Jersey, New York, Texas and Wyoming. CMS will send out contact information for those states to the Program Integrity directors of each state.
- ✓ Who will be held accountable in the audits by DMS or other agencies?  
The pharmacies will be.
- ✓ Can a pharmacy call the prescriber and make a non-compliant hand-written prescription acceptable by getting a telephone order instead?  
Yes.
- ✓ What is each state's responsibility/role?  
It is up to each state to establish its own guidance for compliance and auditing.
- ✓ Can CMS provide a list of authorized vendors for the T-R pads?  
No. CMS will not be providing a list of vendors.
- ✓ Are managed care organizations exempt from this rule?  
Yes, when a managed care entity pays for the medication, the requirements do not apply.

- ✓ If a patient has other insurance and Medicaid is secondary or greater, are they exempt?  
No. If Medicaid pays for any portion of the medication they have to comply with the T-R pad requirements.
- ✓ Is a drug order exempt?  
If the medication is ordered for a Medicaid patient by a prescriber, it is considered to be a prescription and will need to meet the compliance requirements.
- ✓ If a patient presents the pharmacy with a CII prescription on a non-compliant pad, can the pharmacy call the doctor and get a telephone order to correct the prescription and make it compliant?  
No. It's a CII prescription, which cannot be called in to a pharmacy.
- ✓ If a patient presents a prescription to a pharmacy and on the second fill gets in a dispute with the pharmacist, in some states the patient is allowed to get a copy of the prescription back from the pharmacy and go to another pharmacy for filling. Is this prescription now exempt?  
No. It needs to be presented to the new pharmacy on a T-R pad.
- ✓ What about retro-eligibility for Medicaid? If a member has a prescription filled and later becomes Medicaid eligible for that date of service, is that situation exempt?  
No. CMS firmly maintains that if Medicaid is expected or asked to pay any portion of the cost, then the pharmacy will have to go back and get a compliant prescription.
- ✓ What about clinics (such as FQHC's, RHC's, etc.) that have pharmacies on-site? Does the prescription have to be on T-R paper?  
Yes, if it is put in writing at any point along the way. If the MD/NP calls it in to their in-house pharmacy, or faxes it to them, then no T-R paper is necessary. But if a prescription is written and given to a patient to take down to the in-house pharmacy to fill, it MUST be on T-R paper.
- ✓ What about "med order forms" from a LTC facility to a pharmacy?  
If drugs fall under 1027(k)(3), or other applicable sections of the SSA mentioned in the 8/17/07 letter to State Medicaid Directors and Medicaid pays for them separately, then the prescription must be on T-R paper. It was suggested that each state get their own attorneys to provide an interpretation for them.
- ✓ What are the "other specified institutions and clinical settings" mentioned in the 8/17/07 letter to State Medicaid Directors? How are they defined?  
It was suggested that each state gets their own attorneys to look at the applicable statutes, which do have a list of these entities.
- ✓ What is the definition of a "managed care entity" that would be exempt from these requirements? Does a PCCM program qualify for an exemption?  
It was suggested that a PCCM program does not qualify, and each state should have their own attorneys look at Section 1903(i) of the SSA and provide them with an interpretation.